रजिस्टर्ड नं० पी० ६७

राजपत्र, हिमाचल प्रदेश

(असाधारण)

हिमाचल प्रदेश राज्यशासन द्वारा प्रकाशित

शिमला, शुक्रवार, २३ मई, १९६९/२ ज्येष्ठ, १८९१

GOVERNMENT OF HIMACHAL PRADESH

MEDICAL AND PUBLIC HEALTH DEPARTMENT

NOTIFICATION

Simla-4, the 11th March, 1969

No. 2-80/68-Med. II.—The Drugs and Cosmetics (Third Amendment) Rules, 1968, amending the Drugs and Cosmetics Rules, 1945, framed by the Government of India, under section 12 and 13 of the Drugs and Cosmetics Act, 1940, and notified vide Government of India, Ministry of Health, Family Planning and Urban Development (Department of Health and Urban Development) notification No. F. 1-20/64-Drugs, dated the 26th October, 1968, are hereby re-published in the Rajpatra of Himachal Pradesh Government, for the information of the general public and all concerned in Himachal Pradesh.

By order,
S. C. JAIN,
Secretary (Medical).

GOVERNMENT OF INDIA
MINISTRY OF HEALTH, FAMILY PLANNING AND URBAN DEVELOPMENT
(DEPARTMENT OF HEALTH AND U.D.)
NOTIFICATION

New Delhi, the 26th October, 1968

No. F.1-20/64-Drugs.—In exercise of the powers conferred by section 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, the same having been previously published, as required by the said sections, namely:—

1. These rules may be called the Drugs and Cosmetics (Third Amendment) Rules, 1968.

2. In the Drugs and Cosmetics Rules, 1945, (hereinafter referred in as the said Rules),

in rule 69-A, after sub-rule (3), the following sub-rule shall be added, namely:—

"(4) If the licensing authority is satisfied that a loan licence is defaced, damaged or lost or otherwise rendered useless, he may, on payment of a fee of rupees twenty-five issue a duplicate licence."

3. For rule 74 of the said rules, the following rule shall be substituted, namely:—

"**74.** *Conditions of licence in Form* 25.—A licence in Form 25 shall be subject to the conditions stated therein and to the following further conditions, namely:—

(*a*) the licensee shall provide and maintain staff, premises and equipment as specified in rule 71;

(*b*) the licensee shall comply with the provisions of the Act and of these rules and with such further requirements, if any, as may be specified in any rules subsequently made under Chapter IV of the Act: provided that where such further requirements are specified in the rules, these would come into force, four months after publication in the Official Gazette;

(*c*) the licensee shall either in his own laboratory or in any other laboratory approved by the licensing authority test each batch or lot of the raw material used by him for the manufacture of his products and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule U. The records or registers shall be retained for a period of *five years* from the date of manufacture;

(*d*) the licensee shall keep records of the details of manufacture as per particulars given in Schedule U of each batch of the drugs manufactured by him and such records shall be retained for a period of five years;

(*e*) the licensee shall allow an Inspector, authorised by the licensing authority in that behalf, to enter, with or without prior notice, any premises and to inspect the plant and the process of manufacture and the means employed in standardising and testing the drugs;

(*f*) the licensee shall allow an Inspector, authorised by the licensing authority under the provisions of clause (*e*) to inspect all registers and record maintained under these rules and to take sample of the manufactured drugs and shall supply to such Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and the rules thereunder have been observed;

(*g*) the licensee shall, from time to time, report to the licensing authority and changes in the expert staff responsible for the manufacture or testing of the drugs and any material alterations in the premises or plant used for the purpose which have been made since the date of the last inspection made on behalf of the licensing authority;

(*h*) the licensee shall on request furnish to the licensing authority or such authorities as the licensing authority may direct, from every batch of the drug, or from such batch or batches of drugs as the licensing authority may from time to time specify, a sample of such quantity as the authority may consider adequate for an examination and if required full protocols of the tests which have been applied;

(*i*) if the licensing authority so directs and if requested by the licensee who had also furnished *prima facie* reasons for such directions, the licensee shall not sell or offer for sale any batch in respect of which a sample is or protocols are furnished under clause (*h*) until a certificate authorising the sale of the batch been issued to him by or on behalf of the licensing authority;

(*j*) the licensee shall on being informed by the licensing authority that any part of any batch of the drug has been found by the licensing authority not to conform with the standards of strength, quality or purity specified in these rules and on being directed so to do, withdraw the remainder of the batch from sale and, so far as may in the particular circumstances of the case be practicable, recall all issues already made from that batch;

(*k*) the licensee shall maintain an Inspection Book in Form 35 to enable an Inspector to record his impressions and the defects noticed,".

4. In Rule 74-A of the said rules,

(*i*) for clause (*d*) the following clause shall be substituted, namely:—

(*d*) "The licensee shall comply with the provisions of the Act and of these rules and with such further requirements, if any, as may be specified in any rules subsequently made under Chapter IV of the Act: Provided that where such further requirements are specified in the rules, these would come into force four months after publication in the Official Gazette".

(*ii*) for clause (*f*), the following clause shall be substituted, namely:—

(*f*) the licensee shall, either in his own laboratory or, in any other laboratory approved by the licensing authority, test each batch or lot of raw material used by him for repacking and also each batch of the product thus repacked and shall maintain records or registers shall be retained for a period of *Five year* from the date of

repacking. The licensee shall allow the Inspector to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and these rules have been observed.

5. After rule 74-A of the said rules, the following rule shall be inserted, namely:—

"74-B". CONDITIONS OF LICENCE IN FORM 25-A:

(1) The licence in Form 25-A shall be deemed to be cancelled or suspended, if the licence owned by the licensee in Form 25 whose manufacturing facilities have been availed of by the licensee is cancelled or suspended as the case may be, under these rules.

(2) The licensee shall comply with the provisions of the Act and of these rules and with such further requirements if any, as may be specified in any rules subsequently made under Chapter IV of the Act: provided that where such further requirements are specified in the rules, these would come into force four months after publication in the Official Gazette.

(3) The licensee shall test each batch or lot of the raw material used by him for the manufacture of his products and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule U. The records or registers shall be retained for a period of *Five years* from the date of manufacture. The licensee shall allow an Inspector to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and these rules have been observed.

(4) The licensee shall either (*i*) provide and maintain to the satisfaction of the licensing authorities adequate staff and adequate laboratory facilities for carrying out tests of the strength, quality and purity of the substances manufactured by him or (*ii*) make arrangements with some institution approved by the licensing authority for such tests to be regularly carried out on his behalf by the institution.

6. In rule 75-A of the said rules, after sub-rule (3), following sub-rule shall be inserted, namely:—

"(4) If the licensing authority is satisfied that a loan licence is defaced, damaged or otherwise rendered useless, he may, on payment of a fee of rupees seventy-five, issue a duplicate licence.".

7. In rule 78 of the said rules,

(*i*) for clause (*c*), the following clause shall be substituted, namely:—

(*c*) (*i*) The licensee shall maintain records of manufacture as per particulars given in Schedule U.

(*ii*) The licensee shall either in his own laboratory or in any laboratory approved by the licensing authority test each batch or lot of the raw material used by him for the manufacture of his product and also each batch of the final product and shall maintain records or

register showing the particulars in respect of such test as specified in Schedule U. The records or registers shall be retained in the case of a substance for which a potency date is fixed for a period of two years from the expiry of such date, and in the case of other substances for a period of five years from the date of a manufacture.

(*iii*) for clause (*k*), the following clause shall be substituted, namely:—

"(*K*) the licensee shall comply with the provisions of the Act and of these rules and with such further requirements, if any, as may be specified in any rules subsequently made under Chapter IV of the Act, provided that where such further requirements are specified in the rules, those would come into force four months after publication in the Official Gazette.

8. After rule 78 of the said rules, the following rule shall be inserted, namely:—

"78-A CONDITIONS OF LICENCE IN FORM 28-A"

(1) The licensee in Form 28-A, shall be deemed to be cancelled or suspended if the licence owned by the licensee in Form 28 whose manufacturing facilities have been availed of by the licensee is cancelled or suspended, as the case may be under these rules.

(2) The licensee shall comply with the provisions of the Act and of these rules and with such further requirements if any, as may be specified in any Rules subsequently made under Chapter IV of the Act: provided that where such further requirements are specified in the rules, those would come into force four months after publication in the official gazette.

(3) The licensee shall test each batch or lot of the raw material used by him for the manufacture of his products and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests as specified in Schedule U. Records or registers shall be retained in the case or a substance for which a potency date is fixed, for a period of two years from the expiry of such date and in the case of other substances, for a period of five years from the date of manufacture. The licensee shall allow an inspector to inspect all registers and records maintained under these rules and shall supply to the Inspector such information as he may require for the purpose of ascertaining whether the provisions of the Act and these rules have been observed.

(4) The licensee shall either (*i*) provide and maintain to the satisfaction of the licensing authority adequate staff and adequate laboratory facilities for carrying out tests of the strength, quality and purity of the substances manufactured by him or (*ii*) make arrangements with some institution approved by the licensing autority for such tests to be regularly carried out on his behalf by the institution.

9. After Schedule T of the said rules, the following schedule shall be added, namely:—

"SCHEDULE U"

(*See* Rules 74, 74-A, 74-B,78 and 78-A)

I. PARTICULARS TO BE SHOWN IN MANUFACTURING RECORDS

A. SUBSTANCES OTHER THAN PARENTERAL PREPARATION IN GENERAL:

1. Serial number.

2. Name of the product.
3. Lot/Batch size.
4. Lot/Batch Number.
5. Date of commencement of manufacture and date when manufacture was completed.
6. Name of all ingredients, quantities required for the lot/batch size, quantities actually used. (All weighing and measurements shall be checked and initialled by the competent person in the section).
7. Control reference numbers in respect of raw materials used informulation.
8. Date of mixing in case of dry products e.g., powder, powder mixture for capsule products etc.
9. Date of granulation wherever applicable.
10. Weight of granules.
11. Date of compression in case of tablets/date of filling in case of capsules.

11A. Dates of coating wherever applicable.

12. Records of test to be carried out in case of tablets as under:—

(*a*) average weight every thirty minutes.

(*b*) disintegration time as often as practicable.

13. Records of readings taken to check weight variation in case of capsules.
14. Reference to Analytical Report number stating whether of standard quality or otherwise.
15. Records on the disposal of rejected batches and batches withdrawn from the market.
16. Actual production and packing particulars indicating the size and quantity of finished packings.
17. Date of release of finished packing for distribution or sale.
18. In case of Hypodermic tablets and opthalmic preparations which are required to be manufactured under aseptic condition, record shall be maintained indicating the precautions taken during the process of manufacture to ensure that aseptic conditions are maintained.
19. Signature of the Expert Staff responsible for the manufacture.

B. PARENTERAL PREPARATIONS:

1. Serial Number.
2. Name of the product.
3. Lot size.
4. Batch Number (if bulk lot is divided into various batches and processed separately, a batch number distinctly different from that of the bulk lot should be assigned to each of the processed batch).
5. Date of commencement of manufacture and date of completion.

6. Name of all igredients, quantities required for the lot size, quantities actually used. (All weighing and measurements shall be checked and initialled by the competent person in the section.
7. Control reference numbers in respect of raw material used.
8. PH of the Solution wherever applicable.
9. Date and methods of filtration.
10. Sterility test reference on bulk batch wherever applicable (If bulk lot is divided into various batches and processed separately, a batch number distinctly different from that of the bulk lot should be assigned to each of the processed batch).
11. Date of filling.
12. Records of tests employed:—
    (*a*) to ensure that sealed ampoules are leak-proof;
    (*b*) to check the presence of foreign particles;
    (*c*) for pyrogens wherever applicable.
13. Records of sterilisation in case of parentienal preparations which are heat sterilised-including particulars of time, temperature and pressure employed.
14. Number and size of containers filled and number rejected.
15. Reference to Analytical Report numbers stating whether of standard quality or otherwise.
16. Records of the disposal of rejected batch and batches withdrawn from the market.
17. Actual production and packing particulars.
18. Date of release of finished packings for distribution or sale.
19. Particulars regarding the precautions taken during manufacture to ensure that aseptic conditions are maintained.
20. Control reference numbers in respect of the lot of glass containers used for filling.
21. Signature of the Expert Staff responsible for manufacture.

II—RECORDS OF RAW MATERIALS

Records in respect of each raw material shall be maintained indicating the quantity received, control reference numbers, the quantities issued from time to time, the names and batch Nos. of the products for the manufacture of which the quantities have been issued and the particulars relating to the proper disposal of the stocks.

III—PARTICULARS TO BE RECORDED IN THE ANALYTICAL RECORDS

A—Tablets and Capsules:

1. Analytical report number.
2. Name of the sample.
3. Date of receipt of sample.
4. Batch/Lot Number.
5. Protocols of tests applied.

(*a*) Description.

(*b*) Identification.
(*c*) Uniformity of weight.
(*d*) Uniformity of diameter (if applicable).
(*e*) Disintegration Test (time in minutes).
(*f*) Any other tests.
(*g*) Results of assay.

Notes.—Records regarding various tests applied (including reading and calculations) should be maintained and necessary reference to these records should be entered in column 5 above whenever necessary.

6. Signature of the Analyst.
7. Opinion and signature of the approved Analyst.

B—PARENTERAL PREPARATIONS:

1. Analytical report number.
2. Name of the sample.
3. Batch number.
4. Date of receipt of sample.
5. Number of container filled.
6. Number of container received.
7. Protocols of tests applied:

(*a*) Clarity.
(*b*) PH wherever applicable.
(*c*) Identification.
(*d*) Volume in container.
(*e*) Sterility—(*i*) Bulk sample wherever applicable (*ii*) container sample.
(*f*) Pyrogen Test wherever applicable.
(*g*) Toxicity test wherever applicable.
(*h*) Any other tests.
(*i*) Results of assay.

Notes.—Records regarding various tests applied (including reading and calculations) should be maintained and necessary reference to these records should be entered in column 7 above, wherever necessary.

8. Signature of the Analyst.
9. Opinion and signature of the approved Analyst.

PYROGEN TEST:

1. Test Report Number.
2. Name of the sample.
3. Batch number.
4. Number of rabbits used.
5. Weight of each rabbit.
6. Normal temperature of each rabbit.
7. Mean initial temperature of each rabbit.
8. Dose and volume of solution injected into each rabbit and time of injection.
9. Temperature of each rabbit noted at suitable intervals.
10. Maximum temperature.
11. Response.
12. Summed Response.
13. Signature of the Analyst.
    Opinion and signature of the approved Analyst.

TOXICITY TEST:

1. Test Report Number.
2. Name of the sample.
3. Batch number.
4. Number of mice used and weight of each mouse.
5. Strength and volume of the drug injected.
6. Date of injection.
7. Results and remarks.
8. Signature of Analyst.
9. Opinion and signature of the approved Analyst.

C—FOR OTHER DRUGS:

1. Analytical report number.
2. Name of the sample.
3. Batch/lot number.
4. Date of receipt of sample.
5. Protocols of test applied:

   (*a*) Description.
   (*b*) Identification.
   (*c*) Any other tests.
   (*d*) Results of assay.

Note.—Particulars regarding various tests applied (including readings and calculations) shall be maintained and necessary reference to these records shall be entered in column 5 above, wherever necessary.

6. Signature of the Analyst.
7. Opinion and signature of the approved analyst.

D—RAW MATERIALS:—

1. Serial number.
2. Name of the material.
3. Name of the manufacturer/supplier.
4. Quantity received.
5. Invoice/Challan Number and date.
6. Protocols of tests applied.

Note.—Particulars regarding various tests applied (Including reading and calculations) shall be maintained and necessary reference to these records shall be entered in column 6 above, wherever necessary.

E—CONTAINER, PACKING MATERIAL, ETC.—

1. Serial number.
2. Name of the item.
3. Name of the manufacture/supplier.
4. Quantity received.
5. Invoice/Challan number and date.
6. Results of tests applied.

Note.—Particulars regarding various tests applied shall be maintained and necessary reference to these records shall be entered in column 6 above whenever necessary.

7. Remarks.
8. Signature of the examiner.

Note.—The foregoing provisions represent the minimum requirements to be complied with by the licensee. The licensing Authority, may, however, direct the nature of records to be maintained by the licensee for such products as are not covered by the categories described above.

2. The Licensing Authority may permit the licensee to maintain records in such manner as are considered satisfactory, provided the basic requirements laid down above are complied with.

3. The Licensing Authority may at its discretion direct the licensee to maintain records for such additional particulars as it may consider necessary in the circumstances of a particular case".

L. K. MURTHY,
Under Secretary to the Government of India.

प्रबन्धक, हिमाचल प्रदेश शासन मुद्रणालय, शिमला-३ द्वारा मुद्रित तथा प्रकाशित ।